

Claims:

1. A method of diagnosing chronic inflammatory bowel disease comprising:
detecting at least one gene expression product of the *regenerating (REG)* gene
5 family in a body sample of a first human, wherein the first human is suspected of having
chronic inflammatory bowel disease;
identifying the first human as having chronic inflammatory bowel disease if the
gene expression product is detected.

10 2. The method of claim 1 wherein an amount of the gene expression product
detected in the body sample of the first human is compared with an amount of the gene
expression product detected in a body sample of a second human, wherein the second
human is healthy, wherein more of the gene expression product detected in the body
sample of the first human than in the body sample of the second healthy human, confirms
15 chronic mucosal injury in the first human.

20 3. The method of claim 1 wherein the gene expression product of the *REG* gene
family is selected from the group consisting of gene expression products of *pancreatic
stone protein (PSP)*, *pancreatitis-associated protein (PAP)*, *human pancreatic beta cell
growth factor (INGAP)*, and *regenerating gene homologue (REGH)* genes.

4. The method of claim 1 wherein the chronic mucosal injury is selected from the

group of diseases consisting of ulcerative colitis and Crohn's disease.

5. The method of claim 1 wherein the body sample is blood.
- 5 6. The method of claim 1 wherein the body sample is plasma.
7. The method of claim 1 wherein the body sample is serum.
8. The method of claim 1 wherein the body sample is small intestine or colon tissue.
- 10 9. The method of claim 1 wherein the gene expression product is a polypeptide.
10. The method of claim 9 wherein an antibody is used to detect the polypeptide.
- 15 11. The method of claim 10 wherein an assay selected from the group consisting of Western blot assay, immunoprecipitation assay, enzyme linked immunoabsorbant assay, quantitative antigen capture-based immunoassay, and radioimmunoassay is used to detect the polypeptide.
- 20 12. The method of claim 1 wherein the gene expression product is mRNA.
13. The method of claim 12 wherein an assay selected from the group consisting of

Northern blot assay, DNA array, and ~~ribonuclease~~ protection assay, is used to detect the mRNA.

14. A method to aid in the differentiation of chronic mucosal injury from common acute inflammatory colon disorder and common non-inflammatory benign colon disorder in a human with symptoms of bowel disease comprising:

comparing (a) the amount of at least one gene expression product of the *REG* gene family in a body sample of a first human who is suspected of having bowel disease, with (b) the amount of the gene expression product in a body sample of a second human who is healthy;

identifying the first human as having chronic mucosal injury if the body sample of the first human contains more of the gene expression product than the body sample of the second human.

15. The method of claim 14 wherein the gene expression product of the *REG* gene family is selected from the group consisting of gene expression products of *pancreatic stone protein (PSP)*, *pancreatitis-associated protein (PAP)*, *human pancreatic beta cell growth factor (INGAP)*, and *regenerating gene homologue (REGH)* genes.

16. The method of claim 14 wherein the body sample is blood.

17. The method of claim 14 wherein the body sample is plasma.

18. The method of claim 14 wherein the body sample is serum.

19. The method of claim 14 wherein the body sample is small intestine or colon
5 tissue.

20. The method of claim 14 wherein the gene expression product is a polypeptide.

21. The method of claim 20 wherein an antibody is used to quantitate the
10 polypeptide.

22. The method of claim 21 wherein an assay selected from the group consisting of
Western blot assay, immunoprecipitation assay, enzyme linked immunoabsorbant assay,
quantitative antigen capture-based immunoassay, and radioimmunoassay is used to
15 quantitate the polypeptide.

23. The method of claim 14 wherein the gene expression product is mRNA.

24. The method of claim 23 wherein an assay selected from the group consisting of
20 Northern blot assay, DNA array, and ribonuclease protection assay, is used to detect the
mRNA.

25. A method to determine degree of injury to small intestine or colon tissue of a human with chronic mucosal injury comprising the steps of:

determining a quantity of a gene expression product of the *REG* gene family in a body sample of a human having chronic mucosal injury,

5 correlating the quantity of the gene expression product with the degree of injury to the small intestine or colon.

26. The method of claim 25 wherein the gene expression product of the *REG* gene family is selected from the group consisting of gene expression products of *pancreatic stone protein (PSP)*, *pancreatitis-associated protein (PAP)*, *human pancreatic beta cell growth factor (INGAP)*, and *regenerating gene homologue (REGH)* genes.

27. The method of claim 25 wherein the chronic mucosal injury is selected from the group of diseases consisting of ulcerative colitis and Crohn's disease.

28. The method of claim 25 wherein the body sample is blood.

29. The method of claim 25 wherein the body sample is plasma.

30. The method of claim 25 wherein the body sample is serum.

31. The method of claim 25 wherein the body sample is small intestine or colon

tissue.

32. The method of claim 25 wherein the gene expression product is a polypeptide.

5 33. The method of claim 32 wherein an antibody is used to quantitate the polypeptide.

34. The method of claim 33 wherein an assay selected from the group consisting of Western blot assay, immunoprecipitation assay, enzyme linked immunoabsorbant assay, quantitative antigen capture-based immunoassay, and radioimmunoassay is used to quantitate the polypeptide.

10 35. The method of claim 25 wherein the gene expression product is mRNA.

15 36. The method of claim 35 wherein an assay selected from the group consisting of Northern blot assay, DNA array, and ribonuclease protection assay is used to detect the mRNA.

20 37. A method of monitoring the efficacy of therapy for chronic mucosal injury in a human body sample comprising the steps of:

quantitating at least one gene expression product of the *REG* gene family in a body sample of a human who has been subjected to therapy for chronic mucosal injury;

comparing the quantity of expression product in said sample to the quantity of said gene expression product in a matched body sample of the human at an earlier time, wherein a reduction in the quantity of said gene expression product after therapy is an index of efficacy of the therapy.

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38. The method of claim 37 wherein the gene expression product of the *REG* gene family is selected from the group consisting of gene expression products of *pancreatic stone protein (PSP)*, *pancreatitis-associated protein (PAP)*, *human pancreatic beta cell growth factor (INGAP)*, and *regenerating gene homologue (REGH)* genes.

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39. The method of claim 37 wherein the chronic mucosal injury is selected from the group of diseases consisting of ulcerative colitis and Crohn's disease.

40. The method of claim 37 wherein the body sample is blood.

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41. The method of claim 37 wherein the body sample is plasma.

42. The method of claim 37 wherein the body sample is serum.

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43. The method of claim 37 wherein the body sample is small intestine or colon tissue.

44. The method of claim 37 wherein the gene expression product is a polypeptide.

45. The method of claim 44 wherein an antibody is used to quantitate the polypeptide.

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46. The method of claim 45 wherein an assay selected from the group consisting of Western blot assay, immunoprecipitation assay, enzyme linked immunoabsorbant assay, quantitative antigen capture-based immunoassay, and radioimmunoassay is used to quantitate the polypeptide.

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47. The method of claim 37 wherein the gene expression product is mRNA.

48. The method of claim 47 wherein an assay selected from the group consisting of Northern blot assay, DNA array, and ribonuclease protection assay is used to detect the mRNA.

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49. A method of screening compounds for anti-chronic mucosal injury activity comprising:

contacting a colonic cell expressing a gene which is a member of the *REG* gene family with a test compound and;

quantitating expression of the *REG* gene, wherein a test compound which decreases expression of the gene is identified as a potential compound for treating

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chronic mucosal injury.

50. The method of claim 49 wherein the gene is selected from the group consisting of
pancreatic stone protein (PSP), *pancreatitis-associated protein (PAP)*, *human*
5 *pancreatic beta cell growth factor (INGAP)*, and *regenerating gene homologue (REGH)*
genes.

51. A method of diagnosing ulcerative colitis comprising:
detecting an mRNA which is expressed by a gene represented by a Hs.111244
10 polynucleotide in a body sample of a first human who is suspected of having ulcerative
colitis;
identifying the human as having ulcerative colitis if said mRNA is detected.

52. The method of claim 51 wherein an amount of the mRNA detected in the body
15 sample of the first human is compared with an amount of the mRNA in a body sample of
a second human who is healthy;
identifying the first human as having ulcerative colitis if the body sample of the
first human contains more of the mRNA than the body sample of the second human.

20 53. The method of claim 51 wherein the body sample is blood.

54. The method of claim 51 wherein the body sample is plasma.

55. The method of claim 51 wherein the body sample is serum.

56. The method of claim 51 wherein the body sample is small intestine or colon
5 tissue.

57. The method of claim 51 wherein an assay selected from the group consisting of
Northern blot assay, DNA array, and ribonuclease protection assay is used to detect the
mRNA.

10 58. A method to aid in the differentiation of ulcerative colitis from common acute
inflammatory colon disorder, common non-inflammatory benign colon disorder, and
Crohn's disease in a human with symptoms of bowel disease comprising:

15 comparing the amount of mRNA which is expressed by a gene represented by a
Hs.111244 polynucleotide in a body sample of a first human suspected of having bowel
disease with the amount of the mRNA in a comparable body sample of a second human
who is healthy, wherein a body sample of the first human which contains more of the
mRNA than the body sample of the second human identifies the first human as having
ulcerative colitis.

20 59. The method of claim 58 wherein the body sample is blood.

60. The method of claim 58 wherein the body sample is plasma.

61. The method of claim 58 wherein the body sample is serum.

5 62. The method of claim 58 wherein the body sample is small intestine or colon tissue.

10 63. The method of claim 58 wherein an assay selected from the group consisting of Northern blot assay, DNA array, and ribonuclease protection assay is used to detect the mRNA.

64. A method to determine degree of injury to small intestine or colon tissue of a human with ulcerative colitis comprising the steps of:

15 determining a quantity of an mRNA which is expressed by a gene represented by a Hs.111244 polynucleotide in a body sample of a first human having ulcerative colitis;

correlating the quantity of the mRNA with the degree of injury to the small intestine or colon.

20 65. The method of claim 64 wherein the body sample is blood.

66. The method of claim 64 wherein the body sample is plasma.

67. The method of claim 64 wherein the body sample is serum.

68. The method of claim 64 wherein the body sample is small intestine or colon
5 tissue.

69. The method of claim 64 wherein an assay selected from the group consisting of
Northern blot assay, DNA array, and ribonuclease protection assay is used to detect the
mRNA.

10 70. A method of monitoring the efficacy of therapy for ulcerative colitis in a human
body sample comprising the steps of:

quantitating an mRNA which is expressed by gene represented by a Hs.111244
polynucleotide in a body sample of a human who has been subjected to therapy for
15 ulcerative colitis;

comparing the quantity of the mRNA in said sample to the quantity of said
mRNA in a matched body sample of the human at an earlier time, wherein a reduction
in the quantity of said mRNA after therapy is an index of efficacy of the therapy.

20 71. The method of claim 70 wherein the body sample is blood.

72. The method of claim 70 wherein the body sample is plasma.

73. The method of claim 70 wherein the body sample is serum.

74. The method of claim 70 wherein the body sample is small intestine or colon
5 tissue.

75. The method of claim 70 wherein an assay selected from the group consisting of
Northern blot assay, DNA array, and ribonuclease protection assay is used to detect the
mRNA.

10 76. A method of screening compounds for anti-ulcerative colitis activity comprising:
contacting a colonic cell expressing an mRNA which is expressed by a gene
represented by a Hs.111244 polynucleotide with a test compound and;
quantitating expression of the mRNA by the cell, wherein a test compound which
15 decreases expression of the mRNA is identified as a potential compound for treating
ulcerative colitis.